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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/942,369	10/02/1997	CHUN-MING CHEN	03604-0010-US00	8043

7590 01/03/2003

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EXAMINER

MORAN, MARJORIE A

ART UNIT	PAPER NUMBER
1631	43

DATE MAILED: 01/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicant No.	Applicant(s)
	08/942,369	CHEN ET AL.
	Examiner	Art Unit
	Marjorie A. Moran	1631

-- The MAILING DATE of this communication appears in the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 26 September 2002.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 20-24,26 and 31-43 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 20-24,26 and 31-43 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____.

2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.

6) Other: _____.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Claims 20-24 and 31 are again rejected, as previously set forth in the office action of 3/27/02, and new claims 32-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over JOHNSON (US 4,077,845) in view of LIBMAN *et al.* (US 4,046,138) and THALLER *et al.* (J. Clinical Microbiol. (4/1988), vol. 26 (4), pp. 791-793).

Applicant's states in the response filed 10/1/02 that the rejection of claims 20-24 and 31 are traversed for "reasons of record," however, no arguments with regard to this rejection are of record. The "remarks" attached to the Interview Summary of 9/10/02 are clearly labeled "DRAFT FOR DISCUSSION PURPOSES ONLY" and are not arguments of record. As no arguments have been set forth with regard to the rejection of claims 20-24 and 31, the rejection of claims 20-24 and 31 is maintained.

New claims 32-36 recite a method and limitations similar to those of claims 20-24, wherein claim 32 further limits the uropathogenic specific medium to comprise a methyl-umbelliferyl substrate, which when metabolized, indicates the presence of uropathogens in the sample.

JOHNSON teaches a process (method) for detecting and determining the susceptibility of specific microorganisms to antibiotics wherein a clinical (urine) sample is added to separate wells of a microtiter plate, which wells comprise a selective culture medium or blends of the selective culture medium and known antibiotics, the plate is cultured, then the wells examined for growth of microorganisms (col. 10, line 45-col. 12, line 2 and col. 7, lines 33-36). JOHNSON further teaches that his method and device may be used to analyze urinary pathogens,

specifically *Escherichia coli*, *Klebsiella*, *Enterobacter*, and *Proteus* spp. (col. 3, lines 31-36).

JOHNSON teaches that his sample may be urine, blood or spinal fluid, and that growth in individual growth wells permits a positive test for indication of organisms (col. 7, lines 39-46).

JOHNSON does not specifically teach a medium capable of sustaining growth of total microbial organisms nor a medium comprising a fluorogenic or chromogenic substrate.

LIBMAN teaches a device and method for detecting contaminating microorganisms (pathogens) in a urine sample wherein the sample is cultured on two or more different media, selective and nonselective (col. 3, lines 64-67). LIBMAN teaches that his nonselective media supports growth of urinary pathogens and contaminants.

THALLER teaches a selective, differential medium to screen for common gram-negative urinary tract pathogens (abstract), wherein the medium is inhibitory to growth of gram-positive organisms (p. 792, right column). THALLER teaches that metabolism of chromogenic and/or fluorogenic substrates, specifically a methyl-umbelliferyl-glucuronide, in her medium can produce detectable signals whereby urinary pathogens are detected (p. 792, left column and Table 1). THALLER specifically teaches that microorganisms detected using her medium include *E. coli*, *Klebsiella* species, an *Enterobacter* species, *Proteus* species, *Morganella*, and *Providencia* (Table 1). THALLER teaches that her medium provides several improvements over other selective media used in methods of detecting urinary pathogens (p. 792, right column).

It would have been obvious to one of ordinary skill in the art at the time of invention to include the nonselective medium of LIBMAN in the method of JOHNSON where the motivation would have been to provide a positive control for microorganismal growth, as suggested by JOHNSON. It would also have been obvious to use the selective medium of THALLER as the selective medium in the method of JOHNSON where the motivation would have been to "analyze very selectively" for organisms causing an infection (JOHNSON, col. 3, lines 31-35) in

order to presumptively identify the causative organisms in order to determine an appropriate course of treatment, as suggested by both LIBMAN (col. 2, lines 48-53) and JOHNSON (col. 3, lines 30-39). One would also have been motivated to use the selective medium of THALLER in the method of JOHNSON and LIBMAN because it is an improvement over other selective medium such as that taught by LIBMAN. One skilled in the art would reasonably have expected success in incorporating the selective and nonselective media of THALLER and LIBMAN in the method of JOHNSON because JOHNSON teaches sustenance of growth of total microbial organisms, which implies use of a nonselective medium, and because JOHNSON specifically teaches use of selective media. One skilled in the art would also have reasonably expected success in using the T-mod medium of THALLER as a selective medium in the method of JOHNSON because the THALLER specifically teaches that her medium is a selective, differential medium which may be used to successfully detect and identify gram-negative microorganisms in urine samples (p. 791), and specifically teaches that metabolism of a methyl-umbelliferyl substrate indicates the presence of *E. coli*, which are uropathogens.

Claims 38-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over JOHNSON (US 4,077,845) in view of LIBMAN *et al.* (US 4,046,138) and THALLER *et al.* (J. Clinical Microbiol. (4/1988), vol. 26 (4), pp. 791-793) as applied to claims 20-24 above, and further in view of ODAKA *et al.* (JP 04051890).

New claims 38-42 recite a method and limitations similar to those of claims 20-24, wherein claim 38 further limits the uropathogenic specific medium to comprise a yeast extract. JOHNSON, LIBMAN, and THALLER make obvious a method of simultaneously detecting target microorganisms in a biological sample and determining susceptibility of the

microorganisms to antimicrobial agents using a nonspecific medium and a medium specific for urinary gram negative pathogens, as set forth above. THALLER does not teach that her uropathogenic specific medium comprises yeast extract.

ODAKA teaches a culture medium to enhance growth and rapid detection of *E. coli*, a known uropathogen, and specifically teaches that methyl-umbelliferyl substrates can be detected in a medium comprising yeast extract (abstract).

It would have been obvious to one of ordinary skill in the art at the time of invention to have added the yeast extract of ODAKA to the medium in the method of JOHNSON, LIBMAN, and THALLER where the motivation would have been to enhance growth of *E. coli* and allow for more rapid detection of uropathogens, as taught by ODAKA. One skilled in the art would reasonably have expected success in using a medium comprising the yeast extract of ODAKA to detect uropathogens (e.g. *E. coli*) in the method of JOHNSON, LIBMAN, and THALLER because both ODAKA and THALLER teach use of their media to differentially detect *E. coli* using methyl-umbelliferyl substrates.

Claim 26 is again rejected, as previously set forth in the office action of 3/27/02, and new claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over JOHNSON (F) in view of LIBMAN *et al.* (H) and THALLER *et al.* (J. Clinical Microbiol. (4/1988), vol. 26 (4), pp. 791-793) as applied to claims 20 and 32 above, and further in view of BROCCO (E).

New claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over JOHNSON (F) in view of LIBMAN *et al.* (H), THALLER *et al.* (J. Clinical Microbiol. (4/1988), vol. 26 (4), pp. 791-793), and ODAKA *et al.* (JP 04051890) as applied to claim 40 above, and further in view of BROCCO (E).

Applicant has not set forth arguments with regard to the rejection of claim 26, therefore the rejection is maintained.

Applicant claims methods of simultaneously detecting urinary pathogens in a biological sample and determining susceptibility of the pathogens to antimicrobial agents, as set forth above. Applicant further limits the antimicrobial agents to amoxicillin, clavulanic acid/amoxicillin, or enrofloxacin.

JOHNSON in view of LIBMAN and THALLER make obvious a method of simultaneously detecting target microorganisms in a biological sample and determining susceptibility of the microorganisms to antimicrobial agents using a nonspecific medium and a medium specific for urinary gram negative pathogens, as set forth above. JOHNSON in view of LIBMAN, THALLER, and ODAKA also make obvious a method of simultaneously detecting target microorganisms in a biological sample and determining susceptibility of the microorganisms to antimicrobial agents using a nonspecific medium and a medium specific for urinary gram negative pathogens, as set forth above. None of JOHNSON, LIBMAN, THALLER, or ODAKA specifically teach amoxicillin, clavulanic acid/amoxicillin, or enrofloxacin.

BROCCO teaches a method of determining susceptibility of uropathogens, to amoxicillin and a clavulanic acid mixture (p. 5, line 8-p. 6, line 7 and p. 9, line 4-p. 10, line 15).

It would have been obvious at the time of invention to include the amoxicillin and clavulanic acid of BROCCO as antimicrobial agents in the method of JOHNSON in view of LIBMAN and THALLER or in the method of JOHNSON, LIBMAN, THALLER, and ODAKA where the motivation would have been to test susceptibility of microorganisms, specifically urinary pathogens/E. coli, to any known antibiotic or mixture of antibiotics, as suggested by JOHNSON, in order to determine an appropriate course of treatment for a subject infected with the microorganisms.

Conclusion

Claims 20-24, 26, and 31-43 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9306 for After Final communications.

Application/Control Number: 08/942,369
Art Unit: 1631

Page 8

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to an LIE, Tina Plunkett, whose telephone number is (703) 305-3524.

MARJORIE MORAN
PATENT EXAMINER

Marjorie O. Moran

December 30, 2002